



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,875	06/18/2001	Lin-feng Chen	UCAL-234	1891

24353 7590 09/22/2004

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,875	CHEN ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 19-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 and 19-31 is/are allowed.
- 6) ☒ Claim(s) 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 7/1/2004, in which claims were amended (claims 1, 7 & 12) and in which several new claims were added. Claims 1-10, 19-42 are pending in the instant application.

Any rejection of record in the previous office actions not addressed herein is withdrawn. As the new rejections made herein were necessitated by applicants' amendment of the claims in the response filed 7/1/2004, this action is FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment of the claims in the response filed 7/1/2004. This is a new matter rejection.**

Each of the claims is broadly directed to a method for identifying an agent that modulates NF-kB activity in transcription of a gene in a eukaryotic cell where the method comprises contacting a candidate agent with a eukaryotic cell *in vitro*, and wherein the contacting is done in the presence of an agent that blocks nuclear export. The method further comprises then

Art Unit: 1636

determining the level of deacetylated RelA binding to I κ B α in the eukaryotic cell nucleus or in a nuclear extract. However, there does not appear to be support in the instant application for the limitation, “contacting a candidate agent with a eukaryotic cell *in vitro*, wherein the contacting is performed in the presence of *an* agent that blocks nuclear export” (examiner’s emphasis added). The passages cited by the response as provided support for the claimed methods (i.e. page 34, paragraph 132 through page 38, paragraph 141) only appear to provide support for a single compound, HDAC3, that acts to block nuclear export in the working examples. The use of a single compound that blocks nuclear export in the working examples is not sufficient to provide literal or inherent support for claiming the use of a broad genus of such compounds. Therefore, the new claims comprise impermissible NEW MATTER.

Claims 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants’ amendment of the claims in the response filed 7/1/2004. This is a new matter rejection.**

Claim 38 recites the phrase “contacting the cell with an antibody that specifically binds acetylated RelA, wherein the contacting is under conditions sufficient for binding of the antibody to detect a level of acetylated RelA”. The term “specifically binds acetylated RelA” are not clearly defined in the instant specification. As the claim is currently written, the term appears to be indefinite in that there is no explicit definition provided by the instant specification of what

Art Unit: 1636

constitutes an antibody that “specifically binds” to acetylated RelA. For example, it is unclear as to how specific with regard to binding other proteins other than RelA the binding activity has to be (e.g. non-specific binding to other proteins bearing an acetylated lysine residue). Further, the claim as written indicates that the binding is necessarily to RelA. The instant specification teaches an example where an anti-acetylated Lysine antibody is used in conjunction with an anti-T7 antibody to identify the presence of an acetylated T7-RelA fusion protein in a sample (e.g. page 21, paragraph 88; page 31, paragraph 122 through page 32, paragraph 124). Thus, the specification provides support for the use of a single species of the recited antibodies where only single very specific set of conditions is applied (i.e. where the T7-RelA fusion protein has already been identified through a different, anti-T7 antibody). It is not even clear that the anti-acetylated Lysine antibody used in the example necessarily satisfies the limitation of “specifically binding” to acetylated RelA. Even if one concedes that the particular example provides support for the use of anti-acetylated Lysine antibodies in conjunction with anti-T7 antibodies, the single working example does not provide support for the broadly claimed method where any antibody that somehow “specifically” recognizes acetylated RelA is used in any set of conditions. Therefore, the instant specification does not provide descriptive support for the broadly claimed genus of antisera that “specifically” bind acetylated RelA under any binding conditions, and the cited phrase further constitutes impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1636

Claims 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by applicants' amendment of the claims in the response filed 7/1/2004. This is a new matter rejection.**

Claim 38 recites the phrase "contacting the cell with an antibody that specifically binds acetylated RelA, wherein the contacting is under conditions sufficient for binding of the antibody to detect a level of acetylated RelA". The term "specifically binds acetylated RelA" are not clearly defined in the instant specification. As the claim is currently written, the term appears to be indefinite in that there is no explicit definition provided by the instant specification of what constitutes an antibody that "specifically binds" to acetylated RelA. For example, it is unclear as to how specific with regard to binding other proteins other than RelA the binding activity has to be (e.g. non-specific binding to other proteins bearing an acetylated lysine residue). Further, the claim as written indicates that the binding is necessarily to RelA. However, the only example provided in the specification does not apparently specifically bind acetylated RelA, but rather binds to an acetylated lysine residue which may be present in any acetylated protein other than RelA. Therefore, it is unclear what is intended by the cited phrase.

Conclusion

Claims 1-10 & 19-31 are allowable. Claims 32-42 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 1636

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gerald G Leffers Jr., PhD
GERRY LEFFERS Primary Examiner
PRIMARY EXAMINER Art Unit 1636